

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 071007/0137

In re application of:
BHATTACHARJEE et al.

Serial No.: 08/886,044

Filing Date: June 30, 1997

Group Art Unit: 1641

Examiner: S. Devi



For: **VACCINE AGAINST GRAM-NEGATIVE
BACTERIAL INFECTIONS**

DECLARATION UNDER 37 CFR §1.132

Assistant Commissioner of Patents
Washington, D.C.

Sir:

I, Alan S. Cross, M.D., declare and say as follows:

1. I am the Alan S. Cross shown as co-inventor on the captioned patent application. I am experienced in the field of vaccines directed against bacterial infections. My curriculum vitae is appended to my prior declaration.

2. An initial human study with a vaccine according to the present invention has recently been completed. Twenty four human volunteers were divided into three groups of eight volunteers each. The three groups were inoculated with J5 *E. coli* LPS/*N. meningitidis* OMP vaccine containing 5, 10 or 25 µg, respectively, based on the weight of the J5 LPS. The subjects in each group were inoculated on days zero, 14 and 28. Six of the subjects received a booster dose at ten months.

3. The vaccine was well-tolerated by all individuals, and increased IgG antibody titer to J5 LPS by 2- to 5-fold over pre-immunization levels in 15/24 volunteers.

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I hereby declare that all the statements made herein of my known knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements are so made punishable by fine or imprisonment, or both, under Section 101 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

July 24, 2000

Date

Alan S. Cross
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